MERCY HOSPITAL
SPRINGFIELD, MASSACHUSETTS

Pharmacy Department
Policy & Procedure

Code: Pharmacy
Nursing

I. **Subject:** Medication Events and Adverse Drug Reactions

II. **Infection Control:** 3

III. **Policy:**

Definitions:

A medication event (error) is defined as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Prescribing events include; order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use.

An Adverse Drug Reactions (ADR) is defined "as a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or the modification of physiological function." Sentinel events are major ADR's defined as "an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof."

Responsibility: RN, RPh, MD

V. **Equipment:**

Incidence Occurrence Report	[see Attachment #1]
Medication Event reporting Form	[see Attachment #2]
Adverse Drug Reaction reporting form	[see Attachment #3]

VI. **Procedure:**

1. In the event that an ADR occurs, the nurse or pharmacist will notify the attending physician. Adverse events will be reported on the Incident /Occurrence Report with all pertinent patient information, documentation of adverse event and any other information required. The physician must indicate all relevant information including course of management and patient's response in the progress notes and/or discharge summary.

The nurse will also notify the Nursing Manager/CNS. ADR's (including Sentinel events) can be reported by physicians and nurses on the ADR hot-line at ext: 4540 or by calling the Clinical Coordinator via beeper: 3084. Medical records, through Information Systems, will report all ADR's captured via E-codes, on a monthly basis to the Clinical Coordinator of Pharmacy. This report will be used to pull all the patient charts, so that they can be reviewed for verification, preventability, causal relationship, management and any follow-up actions. The Pharmacy dept. and Nursing will complete an ADR form on all serious and fatal/life-threatening ADR's. ADR's are also identified by E-codes generated by Medical Records. The Pharmacy dept. investigates all ADR's and Sentinel events and compiles trends in ADR's. Data will be collected, reviewed, monitored and reported as required. Data is then reported to the Pharmacy & Therapeutics Committee, Risk Mgt. and Nursing Executive Com. and to the FDA when necessary. Undesirable patterns will be analyzed for trends in performance. ADR's that are common *or expected* will be filed for trending by physician, drug, area, preventability and management. Those judged severe and unusual will be sent to the FDA via the Med Watch reporting system.

[redacted]

Exhibit 2

If an ADR is judged as preventable or mismanaged, a letter may be sent to the prescribing physician for further clarification. All actions by the P&T Sub-committee will be reported at least quarterly to the full P&T Committee and semi-annually to the QI Committee. All ADR's will also be reported to and included in Quality and Risk Management's hospital-wide report on medication errors/ADR's, incidents and occurrences for overall trending and reporting of trends to the appropriate committees. All reports to the P&T, FDA or letters to the physicians will be maintained by the Director of Pharmacy. Any unresolved issues will be reported to the Chief of Service or Medical Staff as determined by the P&T Committee or Quality Improvement Committee.

2. All medication events must be reported to Quality and Risk Management using the Incident/Occurrence report form and Medication Event Reporting form. The Medication Event Reporting form must be completed by the nurse manager, clinical specialist or supervisor to report the details of the event, type of event, and severity level. This non-punitive reporting system is strictly confidential to promote increased reporting and a review of system issues. A multi-disciplinary group (pharmacists, nurses) will review medication events for trends and perform root cause analysis for events of severity level 3 or 4 and for Sentinel events. Data will be collected, reviewed, monitored and reported as required.

VII. **Documentation:** ADR Report

VIII. **References:** N/A

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Beverly A. Ventura, MBA, BS, RN
Vice President - Patient Care Services

Patrick Cooke, MD
Chairperson, P&T Committee

Date: May 1978
Revised: *3/95, 11/95, 9/96, 10/97, 8/00*